Pharmaceutical Compliance and Regulatory Congress 2009

Compliance Program Elements Track I:

How Program Management Can Keep You On Track

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In This Session

- Guide attendees on the "what" and "how" of compliance program operations
  - What is Program Management?
  - Skill Set of an Effective Program Manager
  - Keep on Track – What?
  - Keep on Track – How?
  - How Technology Can Help
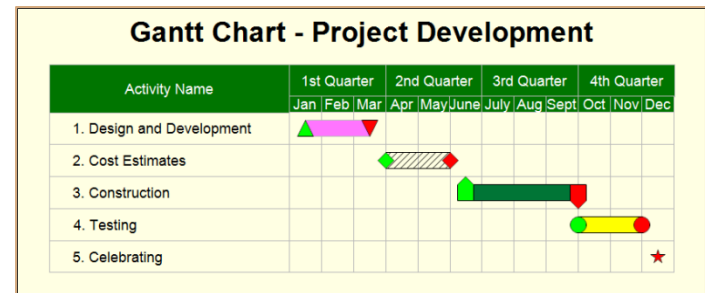 - Challenges & Remedies
  - Key Takeaways

What is Program Management?

- Program Management brings structure and follow-through to your compliance initiatives
- Oversee multiple projects that may be related by:
  - Compliance area (i.e. Sample Accountability, Interactions with HCPs)
  - System (CRM system)
  - Mandate (Corporate Integrity Agreement)
- Program View = Consolidated view of all projects within the program
- Overseeing multiple projects means balancing:
  - Differing priorities
 - Differing timelines
  - Differing sponsors

What is Program Management?

- Project Management & Planning
  - Timing
  - Scope
  - Resources
  - Budget
  - Tracking and follow-through
  - Issues management
- Measurement
- Risk & Contingency Management
- Procurement Management (e.g. vendor selection)
- Reporting
- Budget Management
- Resource Management (internal and external)
- Manage dependencies within and across projects

Gantt Chart - Project Development

Activity Name	1st Quarter			2nd Quarter			3rd Quarter			4th Quarter		
	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec
1. Design and Development												
2. Cost Estimates												
3. Construction												
4. Testing												
5. Celebrating												

Program Manager's Responsibilities

- Oversee the program, which may include managing multiple project plans
- Know the right resources to engage & leverage these resources and their capabilities
- Track progress and report status both at the project and program level
- Escalate and manage issues
- Manage change (e.g. scope creep, change control)
- Maintain focus on the overall compliance program
- Accountability for the successful execution of the program
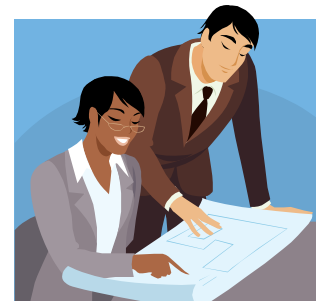
Skill Set of an Effective Program Manager

- Relationship building & People management
  - Influence without authority
  - Provide guidance to team members and business partners
  - Manage communications
  - Facilitator
- Workplan management
  - Understand dependencies across initiatives
  - Drive resources and tasks to completion
- Problem solving
  - Know when to escalate and who to work with when issues arise
- Risk management
  - Know how to identify risks and make sure they are mitigated or escalated
- Experience in process improvements, technology implementations, and other similar programs within the organization

Keep On Track – What?

- 7 Elements of an Effective Compliance Program
  1. Policies and procedures
  2. Compliance Officer and Compliance Committee
     - Steering committee (e.g. CIA)
     - Compliance Council/ committee
  3. Training and education
  4. Lines of communication
     - Internal
     - External
  5. Internal monitoring and auditing
  6. Enforcing standards and disciplinary guidelines
  7. Responding to detected problems and corrective actions

Beware of silos!

Keep On Track – What?

- Compliance requirements
  - CIA
  - Board/Management (SBCE)
  - External audits
  - Mergers/acquisitions (compliance impact)
  - New / changed regulation
- Compliance risk management
- Key projects
- Finances

Keep On Track – How?

- Project Management
  - Right resources on hand with the right skill sets
- Analysis and trending
  - Compare and tie together silos of information
- Reporting
  - When - monthly, quarterly, real-time
  - How – periodic summaries/metrics - all areas of 7 elements
  - Manual vs electronic/system
- Observation/ Discussion
  - Direct line to Chief Compliance Office
  - Interaction with other experienced resources
- Technology
  - Automation of compliance processes
  - Monitoring and reporting
  - Consistency and repeatability

Relationships and proactive interactions are key to effective program management!

Keep On Track – How?

Corporate Compliance Program Dashboard - As of {Reporting Period}

	Overall Summary / BU Avg	Business units Corporate	BU 1	BU 2	BU 3	BU 4	BU 5	BU 6	BU 7	BU 8
Training Requirements										
% Complete	98%	98%	99%	98%	99%	97%	95%	99%	97%	100%
% Incomplete	1%	1%	1%	0%	1%	0%	0%	1%	3%	0%
% Overdue (<2%)	1%	1%	0%	2%	0%	3%	5%	0%	0%	0%
Implemented Programs										
Code of Conduct & Ethics - Policies & Surveys	99%	N/A	100%	100%	100%	98%	N/A	100%	100%	92%
Compliance Risk Management	97%	100%	100%	100%	100%	82%	100%	100%	100%	91%
Foreign Corrupt Practices Act	100%	N/A	N/A	N/A	100%	100%	N/A	100%	100%	100%
Privacy	98%	N/A	100%	100%	100%	87%	100%	100%	100%	100%
Samples Accountability	98%	N/A	100%	100%	100%	87%	100%	100%	100%	100%
In-Process Programs										
Corporate Integrity Agreement	66%	N/A	15%	15%	100%	86%	22%	100%	89%	97%
New State Law Reporting Regulations	41%	47%	31%	31%	40%	38%	24%	24%	69%	67%
Records Rentention	24%	20%	4%	0%	50%	4%	8%	13%	80%	33%

* Yellow background indicates below standard.

Future Programs
Grants Compliance Process Improvements
Policy & Procedure Reviews & Revisions
Speaker Programs Monitoring

Keep On Track – How?

EXAMPLE CELC Dashboard

Compliance and Ethics Leadership Council Dashboard

Allegation and Investigation

Allegation and Investigation -- Violation Detection Metrics

Metric	Period Result	Target	Reported (frequency)	Reported (audience)	Owner
Dollar loss averted because of misconduct detection	100,000	150,000	Quarterly	BOD	TBD
Number of advice calls concerning the Code of Conduct	10	10	Monthly	CCEO	TBD

Allegation and Investigation -- Violation Response and Prevention Metrics

Metric	Period Result	Target	Reported (frequency)	Reported (audience)	Owner
Average cycle time to remediate compliance breaches and deficiencies	3	5	Quarterly	CCEO	TBD

Cultural Indicators

Cultural Indicators -- Cultural Indicators

Metric	Period Result	Target	Reported (frequency)	Reported (audience)	Owner
Percentage of employees who fear retaliation in response to reported allegations	10	5	Monthly	CCEO	TBD

Regulatory Compliance

Regulatory Compliance -- Antitrust/Fair Competition

Metric	Period Result	Target	Reported (frequency)	Reported (audience)	Owner
Percentage of employees who have completed antitrust training (by job category and/or division)					

Keep On Track – How?

- Key Metrics*
  - Procedural Documents
    - *# of documents, by type proposed/ approved monthly/ quarterly*
  - Training
    - *% of employees completing mandatory training by deadline*
  - Auditing and Monitoring
    - *% of repeat observations from monitoring*
    - *% of appropriately executed HCP Agreements*
  - Communications
    - *% of employees reached by communications*
  - Responding to detected problems and corrective actions
    - *# and % of disciplinary actions resulting in terminations*
    - *$ loss averted because of misconduct detection*
  - Other
    - *# reduction in compliance incidents due to training*
    - *Total spend on compliance vendors and systems*

Select metrics that are insightful, actionable, and relevant

*Sources: Compliance and Ethics Leadership Council (CELC), Open Compliance and Ethics Group (OCEG)

Technology

- Implement technologies that drive consistency, efficiency, and repeatability across your 7 elements

Define Policies, Procedures & Controls	Designate High-level Oversight	Implement and Communicate Policies, Procedures & Controls	Develop Accessible Lines of Communication	Audit, Monitor & Report	Ensure Uniform Enforcement	Prevent Further Offenses & Achieve Continuous Improvement
Centralize Knowledge Management	Manage Organizational Structure	Drive Training Plans & E-Learning	Establish & Manage Communication Plans	Standardize Monitoring Auditing & Reporting	Unify GRC Activities and Management on a Single Platform	Track, Investigate & Resolve Issues & Incidents

Technology – Governance, Risk & Compliance Mgt

- Policy , Training & Certification
  - Policy Management
  - Policy Distribution & Certification
  - Learning & Surveys
- Risk & Control Management
  - Risk & Control Inventory
  - Monitoring Risks & Controls
  - Exception Management
- Incident Management
  - Investigations & Corrective Action
- Reports and Audit Results

Challenges & Remedies

Challenges	**Remedies**
1. Staying on track in an ever-changing environment (mergers/acquisitions, changing regulations, internal re-organization, budgets)	1. Report to CCO and have a seat at the table. Function as part of compliance team, not as an independent
2. Satisfying all stakeholders whose priorities may be different (Business, IT, Legal, Compliance, Internal Audit)	2. Relationships, relationships, relationships!
3. Tracking and identifying problems (e.g. legal liability)	3. Discuss before documenting
4. Involvement in many efforts at once	4. Prioritize, plan, define owners, communicate, and get others involved
5. Maintaining a high level of participant engagement	5. Be proactive! Establish regular meetings, make reporting a standard monthly procedure. Have senior management continuously engage participants to re-enforce roles and contribution to overall engagement. Align to objectives/corporate strategy.
6. Reporting the appropriate level of detail	6. Know your audience. Understand the needs and define options
7. Accountability	7. Remember your role and clarify with project leadership. Define owners and decision makers within the business

Key Takeaways

- Don't do this alone – involve management and business up front

- Gauge tolerance level of the organization for oversight and structure

- Relationships, relationships, relationships

- Continuously evaluate 'value-add'

- Reiterate to management their responsibility to *remove barriers* to ensure successful outcome of program

- Use technology for consistency & sustainability, if appropriate

- Standardize processes

Continuous Improvement